

11-13-80

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MEMORANDUM

DATE: November 13, 1980

SUBJECT: Nopocide N-96 Universal Dispersion
EPA File Symbol 2204-RT

FROM: Sherell A. Sterling
FHB/TSS

*See 11-13-80
- 11-20-80*

TO: Henry Jacoby
Product Manager (21)

Applicant: Diamond Shamrock Corp.
Process Chemicals Div.
P. O. Box 2386-R
Morristown, NJ 07960

Active Ingredient:
Chlorothalonil.....48.0%
Inert Ingredients.....52.0%

Background:

This application for registration was submitted with an "alternate" method of support. Acute Oral, Acute Dermal, Eye and Skin Irritation studies were submitted. These studies were conducted by Borriston Research Lab of Temple Hills, MD. Data have been assigned Accession No. 243157.

Recommendations:

1. The Acute Oral study is adequate and acceptable for conditional registration purposes.
2. The Acute Dermal study is adequate and acceptable for conditional registration purposes. However, for future studies you may consider that if data based on testing with at least 5 animals per sex with abraded skin are submitted showing that the LD₅₀ is greater than 2 g/kg with a 24-hour contact period, no further Acute Dermal testing at other dose levels is necessary.

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3. An Acute Inhalation study was not submitted. Please note that under the "alternate" method of support, this study is required on the identical formulation.
4. The Eye Irritation study is considered adequate and acceptable for conditional registration purposes. You may wish to note for future studies that only 9 animals (6 non-irrigated, 3 irrigated) are required for this study.
5. The Primary Dermal Irritation study is adequate and acceptable for conditional registration purposes.
6. The signal word, based on the Eye Irritation study, is DANGER, as proposed by the applicant.
7. FHB/TSS objects to the conditional registration of this product under the "alternate" method of support until an acceptable Acute Inhalation study is submitted. Also, please note the following necessary labeling revisions.

Labeling Recommendations:

1. To the "Environmental Hazards" section please add the following:

"Do not contaminate water by cleaning of equipment or disposal of wastes."
2. Further labeling revisions may be required when Acute Inhalation data are submitted.

Comments:

1. Apparently the "96" in the brand name of this product referred to 96% active ingredient. Since the labeling for this product shows only 48% active ingredient, the product's brand name could be considered misleading.

Review:

1. Acute Oral Toxicity (LD₅₀) Study in Rats with T-126-1; Borriston Research Lab Project No. 209-C; October 1, 1979; Acc. No. 243157.

Procedure: Initially, four range-finding studies were run. For the main study, five dosage levels were chosen - 6.3, 7.9, 10.0, 12.6 and 15.9 g/kg. Five groups of 5M, 5F Sprague-Dawley rats (150-297g) received oral dosages at one of the levels. The test substance was identified as "T-126-1" = "Nopocide N-96 Universal Dispersion."

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Animals were observed for 14 days post exposure. At end of study, survivors were sacrificed; all animals were subjected to necropsies.

Results: Mortalities were: 1/5 M and 3/5 F at 6.3 g/kg; 1/5 M and 2/5 F at 7.9 g/kg; 4/5 M and 4/5 F at 10.0 g/kg; 5/5 M and 5/5 F at 12.6 and 15.9 g/kg. Symptoms included: soft feces, salivation, lethargy. All survivors increased in body weight. Necropsies revealed: mottled lungs in survivors; no gross tissue alterations attributable to treatment. LD₅₀ for M was 8.6 g/kg with 7.0 - 10.7 g/kg 95% confidence range. LD₅₀ for F was 7.0 g/kg with 95% confidence range of 5.1 - 9.7 g/kg. The combined M and F LD₅₀ was 7.8 g/kg with 6.8 - 9.1 g/kg 95% confidence range.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

2. An Acute Dermal Toxicity (LD₅₀) Study: BRL Project No. 209-D; August 3, 1979; Acc. No. 243157.

Procedure: 3M, 3F New Zealand white rabbits (2680 - 2980g) were each subjected to 10 g/kg of the test substance on intact skin for 24 hours. The test substance was identified as "T-126-1" \equiv "Nopocide N-96 Universal Dispersion." Application was under occlusive wrap. Animals were observed for 14 days. At end of study, survivors were sacrificed; all animals were subjected to necropsies.

Results: No mortalities observed; therefore, LD₅₀ is greater than 10 g/kg. Erythema and edema, roughened skin and epidermal sloughing were observed. All animals lost weight between day 1 and day 7; only 3/6 showed weight gain by end of study. Necropsies revealed no gross pathological alterations attributable to treatment.

Study Classification: Core Minimum Data. Abraded sites must be tested.

Toxicity Category: III - CAUTION

3. Eye Irritation Study in Rabbits with T-126-1: BRL Project No. 209-B; June 15, 1979; Acc. No. 243157.

Procedure: 6M, 6F New Zealand white rabbits received 0.1 ml of the test substance in the conjunctival sac. Half of the subjects' treated eyes were subsequently irrigated for one minute with 100 ml of luke-warm water, 20 - 30 seconds post-installation. Draize scoring at 24, 48, 72 hours; 4, 7, 10 and 14 days. The test substance was Nopocide N-96 Universal Dispersion.

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Results: At 24 hours, non-irrigated eyes showed severe corneal opacity (2/6 = 60, 4/6 = 80), iris irritation moderate in 2/6, but not visible in remaining eyes; redness in 1/6 = 2, 5/6 = 3; chemosis in 2/6 = 2, 2/6 = 3, 2/6 = 4; and discharge in 6/6 = 3. Symptoms increased in intensity through day 14. By day 14, corneal opacity in 6/6 = 80; iris not visible in all animals; redness in 6/6 = 3; chemosis in 6/6 = 2 and discharge in 6/6 = 2.

Irrigated eyes at 24 hours showed opacity in 2/6 = 40 and 4/6 = 60; iris irritation in 6/6 = 5; redness in 6/6 = 3; chemosis in 3/6 = 2, 3/6 = 3; discharge in 6/6 = 3. Irritation increased through day 14. By day 14, severe corneal opacity (6/6 = 80) observed; iris irritation not visible; redness in 6/6 = 3; chemosis in 5/6 = 2 and 1/6 = 3; discharge in 6/6 = 2.

Corneal rupture noted in 2 animals, granilomatous growths over corneal surface in several animals and all animals showed loss of hair around treated eye.

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER

4. A Primary Dermal Irritation Study: BRL Project No. 209-E; August 2, 1979; Acc. No. 243157.

Procedure: 6 New Zealand white rabbits received dermal applications of the test substance at each of 4 sites per animal. Application rate was 0.5 ml at each of 4 sites - 2 abraded and 2 intact. Exposure was for 24 hours under occlusive wrap. Draize scoring at 24, 72 hours, 7 days post application. Test substance was Nopocide N-96 Universal Dispersion.

Results: At 24 hours, intact sites showed very slight to severe erythema and slight to severe edema; abraded sites exhibited very slight to severe erythema and slight to severe edema. Irritation increased through 72 hours. By 7 days severe erythema observed in all animals. Fissuring and epidermal sloughing observed. Primary Irritation Index was 5.0.

Study Classification: Core Guideline Data.

Toxicity Category: II - WARNING

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Page 5 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☒ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☐ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) _____.
 - ☐ The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
